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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/937,357

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DA7119US (#90036)

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05/19/2006

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/937,357

**Applicant(s)**

D'ANTONIO ET AL.

**Examiner**

Ann Y. Lam

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 92-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 92-97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The finality of the Office action mailed January 31, 2006 is hereby withdrawn, and prosecution is hereby reopened.

#### ***Status of Claims***

Claims 1-35, 49, 52-58, 60, 61, 63, 68, 88-91 have been cancelled.

Claims 36-48, 50, 51, 59, 62, 64-67, 69-87 have been withdrawn.

Claims 92-97 are currently pending.

#### ***Claim Objections***

Claim 92, 94 and 96, are objected to because of the following informalities:

In claim 92, line 6, "containers" should be --container(s)--.

In claim 94, line 7, "containers" should be --container(s)--.

In claim 96, line 7, "containers" should be --container(s)--.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 92-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 92, line 17, recites "a release structure". It appears that this release structure is the same release apparatus as in line 10. However, the claim recites them as though they are different elements.

Claim 92, line 2, recites "the forward end". There is insufficient antecedent basis for this limitation in the claim. (To overcome this rejection, "the" should be replaced with --a--).

Claim 92, line 6, recites "the injection process". There is insufficient antecedent basis for this limitation in the claim.

Claim 92, line 15, recites "the need". There is insufficient antecedent basis for this limitation in the claim.

Claim 92, line 16, recites "the user". There is insufficient antecedent basis for this limitation in the claim.

Claim 93, line 29, recites "a release structure". It appears that this release structure is the same release apparatus as in line 10. However, the claim recites them as though they are different elements. .

Claim 93, line 7, recites "the forward end". There is insufficient antecedent basis for this limitation in the claim.

Claim 93, line 12, recites "the injection process". There is insufficient antecedent basis for this limitation in the claim.

Claim 93, line 20, recites "the forcing". There is insufficient antecedent basis for this limitation in the claim.

Claim 93, line 25, recites "the replacement". There is insufficient antecedent basis for this limitation in the claim.

Claim 94, line 18, and claim 96, line 18, recite "a release structure. It appears that this release structure is the same release apparatus as in line 11 of each claim respectively. However, the claim recites them as though they are different elements.

Claim 94, line 2, recites "the forward end". There is insufficient antecedent basis for this limitation in the claim.

Claim 94, line 7, recites "the injection process". There is insufficient antecedent basis for this limitation in the claim.

Claim 94, line 16, recites "the need". There is insufficient antecedent basis for this limitation in the claim.

Claim 94, line 17, recites "the user". There is insufficient antecedent basis for this limitation in the claim.

Claim 95, line 30, recites "a release structure". It appears that this release structure is the same release apparatus as recited in line 11. However, the claim recites them as though they are different elements.

Claim 95, line 8, recites "the forward end". There is insufficient antecedent basis for this limitation in the claim.

Claim 95, line 13, recites "the injection process". There is insufficient antecedent basis for this limitation in the claim.

Claim 95, line 21, recites "the forcing". There is insufficient antecedent basis for this limitation in the claim.

Claim 95, line 26, recites "the replacement". There is insufficient antecedent basis for this limitation in the claim.

Claim 96, line 23, recites "releasable locking member". It appears that this releasable locking member is the same latching apparatus as recited in line 11. However, the claim recites them as though they are different elements.

Claim 96, line 2, recites "the forward end". There is insufficient antecedent basis for this limitation in the claim.

Claim 96, line 7, recites "the injection process". There is insufficient antecedent basis for this limitation in the claim.

Claim 96, line 16, recites "the need". There is insufficient antecedent basis for this limitation in the claim.

Claim 96, line 17, recites "the user". There is insufficient antecedent basis for this limitation in the claim.

Claim 96, line 24, recites "the bias". There is insufficient antecedent basis for this limitation in the claim.

Claim 96, line 25, recites "the release". There is insufficient antecedent basis for this limitation in the claim.

Claim 97, line 28, recites "a release structure". It appears that this release structure is the same release apparatus as recited in line 10. However, the claim recites them as though they are different elements.

Claim 97, line 12, recites "the injection process". There is insufficient antecedent basis for this limitation in the claim.

Claim 97, line 20, recites "the forcing". There is insufficient antecedent basis for this limitation in the claim.

Claim 97, line 25, recites "the replacement". There is insufficient antecedent basis for this limitation in the claim.

Claim 97, line 33, recites "the bias". There is insufficient antecedent basis for this limitation in the claim.

Claim 97, line 7, recites "the forward end". There is insufficient antecedent basis for this limitation in the claim.

Claim 97, line 34, recites "the release". There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 92-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Antonio et al., 6,056,716, in view of Kuracina et al., 6,443,929.

D'Antonio et al. disclose the invention substantially as claimed. More specifically, as to claims 92 and 93, D'Antonio discloses a housing (proximal portion of 707, fig. 7E) for housing at least two injectate cartridges (or containers) (845) each of said cartridges having a dispensing channel with an exit nozzle (842', col. 26, lines 52-54), and a plunger (847, col. 26, line 59) for moving through each of the cartridges to dispense injectate from the cartridges;

a holding member (840) for holding the respective injectate cartridges with said dispensing channels directed in a common direction;

a latching and release apparatus (708, see fig. 7E) included in or on said housing for latching said holding member to said housing and for releasing said holding member and the injectate cartridges held thereby for non-contaminating disposal after the injection process (additionally, the container is spaced away from the housing (see 101 in fig. 7E);

a ram apparatus (848) having separate rams (848), each movable with respect to one of said cartridges to move the respective plungers simultaneously for forcing injectate simultaneously from said cartridges through the dispensing channels and the individual exit nozzle (col. 60-63);

a carriage (849) movable from a set position to a dispensing position for moving said ram apparatus at uniform pressures during an injection process

a spring apparatus (227, or see column 26, lines 61-64) for moving said carriage from the set position to the dispensing position;



a carriage resetting apparatus (436) for moving said carriage from the dispensing position to the set position and for recocking said spring apparatus, (see column 10, line 46 – column 11, line 20),

and a releasable latching device for latching said spring apparatus is disclosed, (see column 11, lines 14-20),

said latching and release apparatus (708) supports said holding member spacing the front end of said holding member away from said housing (see figure 7E for assembly) to avoid contact of said housing with any contaminant on the front end of said holding member or the cartridges. (Although holding member 708 is not entirely spaced away from the housing, at least the front end of the holding member is spaced away from the housing)

a release structure (716) operatively connected to said container-holding member and being actuable to release said container-holding member and the injectate containers held in said container-holding member without requiring human contact with said container-holding member or the containers (col. 25, line 65 – col. 26, line 4).

However, D'Antonio et al. do not teach that the release structure is a release button (as claimed in claims 92 and 93). However, this limitation is taught by the combination of the teachings of another embodiment by D'Antonio et al. in view of Kuracina et al., as described further in details below.

More specifically, D'Antonio et al. teach an embodiment in Figure 1 with latches (238 and 239) on a housing such that the latches hold a medicine cartridge (i.e., "injector" 1, shown in Fig. 1, see col. 9, lines 22-23) to be held by an injector system

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(shown in fig. 2A, see col. 9, lines 64-65) by latches (238 and 239). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide latches (238 and 239) as shown in figure 2A as a substitute for the latch (712) shown in figure 7E because D'Antonio et al. show both of these as types of latches for holding a cartridge or multiple cartridges. One of ordinary skill in the art would recognize that one type of latch is an alternative to another type of latch and will provide the same function of retaining a cartridge structure because both types of latches are disclosed by D'Antonio et al. in alternative embodiments. Moreover, one of ordinary skill in the art would have reasonable expectation of success because both of these latches are disclosed by D'Antonio et al. as being capable of retaining a cartridge structure, and also because D'Antonio et al. disclose them as being similarly retained in a injector system, that is, the cartridge structures are disclosed as being held partly inside an injector system and partly outside the injector system in both the embodiments (see fig. 2A and 7E).

Furthermore, Kuracina et al. teach a hypodermic needle having a latching arm (26) a protrusion (21) with a finger pad (27), (see col. 8, lines 36-40; see also col. 17, lines 9-10 disclosing the finger pad as a button). The finger pad (27) is also disclosed as serving to release a needle guard assembly or the like (col. 16, lines 45-48, and see also fig. 49A). The latching arm retains a component in a releasably held position (col. 32, lines 23-27, see also fig. 99). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the latch disclosed by D'Antonio et al. in figure 2A to provide a button as taught by Kuracina et al. to release a component,

such as the cartridges disclosed by D'Antonio et al. One of ordinary skill in the art would recognize that providing a protrusion (21) with a finger pad or button (27) as taught by Kuracina et al. in the D'Antonio et al. latch provides the benefit of more readily permitting a component to be inserted for being retained by the latch and to more readily release the component from the latch, as would be desirable for convenience.

As to claims 93 and 95, D'Antonio et al. disclose at least two injectate cartridges, each having a dispensing channel with an exit nozzle and a plunger for moving through each of the cartridges (see figure 7GG).

As to claims 94 and 95, the button disclosed by Kuracina et al. as described above is considered a trigger as claimed by Applicant because it triggers the release of the latching apparatus.

As to claims 96 and 97, D'Antonio et al. also do not disclose a spring apparatus for biasing the container-holding member (or holding member) to be released from the housing, wherein the releasable locking members releasably lock the container-holding member to the housing against a bias of the spring apparatus. However, Kuracina et al. teach that the latching arm (26) releasably holds a needle guard (22) and a compressed resilient member (19) in a retained position (col. 9, lines 65-67), and upon release of the latching member, the needle guard assembly (22) is urged to the distal end of the hypodermic needle by the extending force of the resilient member (19), (col. 10, lines 13-16.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a resilient member as taught by Kuracina et al. to release an element, such as the container-holding member (i.e., the structure holding

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the cartridges) in the D'Antonio et al. invention because Kuracina et al. teach that a compressed resilient member is useful in releasing an element upon release from a releasing member. One of ordinary skill in the art would recognize the benefits of including a compressed resilient member in facilitating release of an element such as the container-holding member. With respect to the remaining limitations of claims 96 and 97, D'Antonio et al. disclose the limitations as described above (see above regarding claims 92 and 93.)

### ***Response to Arguments***

The Office acknowledges that Applicant cancelled the previously rejected claims in attempt to put the application in condition for allowance. However upon further consideration, the current claims are found to be obvious for the reasons set forth above. The Office apologizes for any inconvenience.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.  5/5/06

  
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